

REMARKS

Claim Rejections – 35 USC § 103

Claims 44-46, 48-52, 70-72 and 74-77 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,090,111 to Nichols in view of U.S. Patent Publication No. 2001/0001119 to Lombardo, and claim 58 stands rejected as being unpatentable over Nichols in view of Lombardo and further in view of U.S. Patent Publication No. 2002/0072751 to Jackson.

Arguments in Support of Patentability

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See Manual of Patent Examining Procedure (MPEP) §2141. While performing this analysis, the cited references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness.

Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396.

For at least the reasons set forth below, the Applicant submits that the pending claims are patentable over the cited references.

Independent Claim 44 and Dependent Claims 45, 46, 48-52 and 77

Independent claim 44 currently stands rejected as being unpatentable over Nichols in view of Lombardo. The Office Action asserts that Nichols discloses the features of independent claim 44 “except for where the upper portion of the receiver member is threaded or a medical implant apparatus having a set screw”. (See page 3). However, in an attempt to overcome this shortcoming, the Office Action asserts that it would have been obvious “to construct the device of Nichols having at least the upper threads or the set screw in view of Lombardo to have a stronger biasing and securing of a longitudinal member to secure the vertebrae”. (See page 3). The Applicant respectfully submits that this assertion has been made in error. Indeed, as discussed in further detail below, Nichols clearly teaches away from the modification proposed by the Office Action, and those skilled in the art would not undertake the same.

In discussing the background of the invention, Nichols indicates the following at column 1, lines 42-52:

[P]rior art devices are connected to the spinal rod by threaded components that necessarily require the application of undesirable torsional forces to the spine. Furthermore, these threaded components can loosen under cyclically applied loads commonly encountered in the spinal column. Clearly, it would be beneficial to provide an improved device for securing spinal rods to the spinous process which provides a wide range of angular adjustability, uniform securement and which does not require the application of undesirable torsional forces during application. (Emphasis added).

In order to address these shortcomings associated with prior art devices, Nichols discloses a device having a receiver member that does not include internal threads engaged by a set screw. More particularly, Nichols discloses a rod securement device 10 that includes a fastener 14, a securement body 16 and a locking member 18. (See column 3, lines 29-31). The locking member 18 “includes a locking mechanism in the form of a pair of laterally opposed tapered wedges 54 and 56 . . . for engaging a corresponding pair of laterally opposed tapered slots 64 and 66 formed in the upper body portion 32 of securement body 16 within the upper cavity portion 38 of interior cavity 34.” (See column 4, lines 46-52). Nichols further discloses that “[t]he tapered wedges 54, 56 and corresponding tapered slots 64, 66 employ inwardly angled sloping locking surfaces to effect positive engagement therebetween.” (See column 4, lines 52-55).

With further regard to the non-threaded locking mechanism arrangement, Nichols discloses the following at column 2, lines 38-47:

Because the tapered wedges of the locking member engage the slots of the reception channel linearly along the axis of the cylindrical spinal rod, the application of undesirable torsional forces to the spine normally generated during the process of tightening a conventional threaded component is avoided. Furthermore, while threaded components can loosen under cyclically applied loads commonly encountered in the spinal column, the locking member remains fixed under such conditions. (Emphasis added).

In view of the foregoing teachings specifically set forth in Nichols, it is respectfully submitted that those skilled in the art would not modify Nichols in the manner suggested in the Office Action. Notably, Nichols clearly teaches away from the application of torsional forces that would accompany the suggested modification of replacing the tapered locking mechanism 18 with a threaded set screw arrangement. Moreover, those skilled in the art would be further lead away from and have no reason for attempting the suggested modification because Nichols also indicates that the locking mechanism 18 achieves enhanced locking of the device 10 relative to conventional threaded components; i.e., it remains fixed and cannot loosen under cyclical loads. Similarly, this teaching of Nichols also undermines the logic (i.e., to have stronger biasing and securing) set forth in the Office Action in support of the suggested modification. Likewise, the rationale required by KSR is also missing. Thus, those skilled in the art would not modify Nichols in the manner asserted in the Office Action.

In view of the foregoing, the Applicant submits that a *prima facie* case of obviousness has not been established with regard to independent claim 44. Accordingly, withdrawal of the rejection of independent claim 44 and allowance of the same is respectfully requested.

Claims 45, 46, 48-52 and 77 depend from independent base claim 44 or an intervening claim and are submitted to be patentable over the Nichols/Lombardo combination for at least the reasons supporting the patentability of independent base claim 44, although further reasons support the patentability of these claims as well.

For example, claim 51 recites “. . . wherein said head of said bone anchor is substantially between said retaining member and said upper opening portion.” However, as illustrated in Figure 4 of Nichols, the head 20 of the fastener 14 is not substantially positioned between the

retaining ring 42 and an upper portion of the body 14. Instead, only a small portion of the head 20 extends above the ring 42.

As another example, claim 77 recites “wherein said part of said bone anchor substantially surrounded by said retaining member is a neck of said bone anchor.” However, as clearly illustrated in Figures 3, 4 and 6 of Nichols, the ring 42 is positioned around the top portion of the head 20 of the fastener 14. Similarly, the neck of the fastener 14 is not substantially surrounded by the ring 42. Accordingly, the subject matter of claim 77 has not been accounted for by the cited combination of references.

Independent Claim 58 and Dependent Claim 55

As indicated above, claim 58 currently stands rejected under 35 U.S.C. §103(a) as being unpatentable over Nichols in view of Lombardo and further in view of Jackson. The Applicant submits that Jackson, in its entirety, does not qualify as prior art against the subject application.

Notably, the subject application is a continuation of Application No. 09/940,902 filed on August 28, 2001. Jackson was filed on November 9, 2001 and claims priority as a continuation-in-part to U.S. Patent Application No. 09/732,528 filed on December 8, 2000. Thus, the only portions of Jackson that may be properly applied against the subject application are those that were originally included in parent U.S. Patent Application No. 09/732,528. In the rejection of independent claim 58, the Office Action relies on Jackson for disclosing reverse angle threads. However, the Applicant notes that the inclusion of reverse angle threads is not disclosed in parent U.S. Patent Application No. 09/732,528. Indeed, the ‘528 application does not discuss or in any way refer to reverse angle threads. Accordingly, the Office Action’s application of Jackson is improper, and the subject matter of independent claim 58, as a whole, has not been accounted for by the Nichols/Lombardo/Jackson combination.

Additionally, for reasons similar to those discussed above with respect to independent claim 44, those skilled in the art would not modify Nichols to include a set screw and internal threads to arrive at the apparatus of independent claim 58. Moreover, as illustrated in Figure 4 of Nichols, the engagement between the tapered wedges 54 and 56 and the tapered slots 64 and 66 already prevents splaying of walls 32a and 32b of the body 16. Likewise, those skilled in the art would have no reason for modifying Nichols to include reverse-angle threads.

In view of the foregoing, the Applicant submits that a *prima facie* case of obviousness has not been established with regard to independent claim 58. Accordingly, withdrawal of the rejection of independent claim 58 and allowance of the same is respectfully requested.

Claim 55 depends from independent base claim 58 and is also patentable over the Nichols/Lombardo/Jackson combination for at least the reasons supporting the patentability of independent base claim 58.

Independent Claim 70 and Dependent Claims 71, 72 and 78-80

Independent claim 70 currently stands rejected as being unpatentable over Nichols in view of Lombardo. Independent claim 70 recites, among other elements and features, that “said upper opening portion is internally threaded.” As acknowledged in the Office Action, Nichols does not disclose this feature. Moreover, for reasons similar to those discussed above with regard to independent claim 44, those skilled in the art would not modify Nichols to include this feature.

In view of the foregoing, the Applicant submits that a *prima facie* case of obviousness has not been established with regard to independent claim 70. Accordingly, withdrawal of the rejection of independent claim 70 and allowance of the same is respectfully requested.

Claims 71 and 72 depend from independent base claim 70 and are patentable over the Nichols/Lombardo combination for at least the reasons set forth above in support of the patentability of independent base claim 70. However, further reasons support the patentability of these claims.

For example, dependent claim 72 further recites “a bone anchor having a head that is at least part spherical and a crown member, said apparatus having a locked condition in which said anchor head contacts said retaining member and said crown member but not said receiver member.” The Applicant submits that the Nichols/Lombardo combination does not disclose or suggest these features. Moreover, the Applicant notes that the Office Action fails to set forth any grounds or bases as to how the cited combination of references disclose these features. Indeed, the Office Action fails to make any reference whatsoever to the recited claim language, and does not even mention the term “crown member”. As indicated above, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. KSR, 82 USPQ2d at 1396 (emphasis added). Since the Office Action fails to set

forth any articulated reasoning and/or rational underpinning to support the legal conclusion of obviousness with regard to the above-discussed language recited in claim 72, a *prima facie* case of obviousness has not been established with regard to claim 72 for this additional reason.

Additionally, claims 78-80 depending either directly or indirectly from independent claim 70 have added via this response. Support for claims 78-80 is found, for example, in paragraph of [0039] and in Figure 6B of the published version of the subject application. Claims 78-80 depend from independent base claim 70 or an intervening claim and are patentable for at least the reasons supporting the patentability of independent base claim 70, although it is also submitted that these claims include features which are not accounted for by the cited combination of references.

Independent Claim 74 and Dependent Claims 75 and 76

Independent claim 74 currently stands rejected as being unpatentable over the Nichols/Lombardo combination. Claim 74 recites, among other features and elements, “wherein said upper opening portion is internally threaded.” As acknowledged in the Office Action, Nichols does not disclose this feature. Moreover, for reasons similar to those discussed above with regard to independent claim 44, those skilled in the art would not modify Nichols to include this feature.

In view of the foregoing, the Applicant respectfully submits that a *prima facie* case of obviousness has not been established with regard to independent claim 74. Accordingly, withdrawal of the rejection of independent claim 74 and allowance of the same is respectfully requested.

Claims 75 and 76 depend from independent base claim 74 and are also patentable over the Nichols/Lombardo combination for at least the reasons supporting the patentability of independent base claim 74, although further reasons support the patentability of these claims. For example, claim 76 further recites “a bone anchor having a head that is at least part spherical and a crown member, said apparatus having a locked condition in which said anchor head contacts said retaining member and said crown member but not said receiver member.” The Applicant submits that the Nichols/Lombardo combination does not disclose or suggest these features. Moreover, the Applicant notes that the Office Action fails to set forth any grounds or bases as to how the cited combination of references discloses these features. Indeed, the Office

Action fails to make any reference whatsoever to the recited claim language, and does not even mention the term “crown member”. As indicated above, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”. KSR, 82 USPQ2d at 1396 (emphasis added). Since the Office Action fails to set forth any articulated reasoning and/or rational underpinning to support the legal conclusion of obviousness with regard to the above-discussed language recited in claim 76, a *prima facie* case of obviousness has not been established with regard to claim 76 for this additional reason.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 44-46, 48-52, 55, 58, 70-72 and 74-80.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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